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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,248	04/08/2004	Eric G. Lovett	GUID.618PA (03-553)	8387

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EXAMINER
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BOCKELMAN, MARK

ART UNIT	PAPER NUMBER
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3766

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/14/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/821,248

Applicant(s)

LOVETT ET AL.

Examiner

Mark W. Bockelman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-95 is/are pending in the application.
- 4a) Of the above claim(s) 41-77 and 81-95 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-40 and 78-80 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4-8-04, 2-4-05, 8-26-05, 11-13-06</u>                         | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION*****Election/Restrictions***

Applicant's election with traverse of invention I, claims 1-40, 78-80 in the reply filed on 11-13-2006 is acknowledged. The traversal is on the ground(s) that the claimed inventions have a common utility and are thus not restrictable. This is not found persuasive because according to applicant's arguments the claim devices won't work without electrodes. The examiner disagrees, applicant's specification states that other sensors may be on the housing and one may simply use the claimed devices of inventions III and IV with the other types of sensors. The devices have no common utility as claimed because as noted by applicant, the devices have no utility without the electrodes. Invention I positively recites the non-intrathoracic electrodes while inventions III and IV do not. Moreover, inventions III and IV do not require the first configurations to be in the absence of the lead electrodes, and III does not require each configuration to be used for both stimulation and sensing. Finally, the types of electrodes specified in the claims of inventions III and IV are merely intended use, all that is claimed is the controller and its ability to connect to various electrodes, whatever their intended use may be.

The requirement is still deemed proper and is therefore made FINAL.

***Specification***

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP

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§ 608.01(o). Correction of the following is required: The specification lacks antecedent basis for each of the means clauses recited in claims 78-80.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 20 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claim recites heart chambers as part of the invention rather than as an intended use, which thus includes part of a human within its scope, which is impermissible under 35 USC 101.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 78-80 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 78-80 have no corresponding structure identified in the specification to allow the examiner to identify the elements and scope of the claims. The examiner hereby requires the applicant to amend the specification to identify all of the elements that correspond to their "means" elements.

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-40, 78-80 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 1, 32, 78 and 79 state that the various configurations can be accomplished by using one or more subcutaneous electrodes and one or more intrathoracic electrodes. The examiner cannot find a teaching in the specification that would allow each of these configurations to be carried out with only one electrode each. It would appear that applicant's require at least two subcutaneous electrodes to provide a complete circuit. Applicant's figures 6-8 only show one subcutaneous electrode, it is not understood how pacing and or defibrillation can be carried out by such without a return pathway. In addition, applicant's specification does not show a single configuration in which sensing and stimulation take place. It would appear that according to applicant's specification the device requires switching from sensing configuration to a stimulation configuration or one would short circuit the other.

***Claim Rejections - 35 USC § 102***

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-6, 40, 78-80 are rejected under 35 U.S.C. 102(b) as being anticipated by KenKnight USPN 6,148,230. KenKnight teach an implantable stimulator with an intrathoracic lead 10 and a subcutaneous lead 20. The subcutaneous lead has sensing electrodes 24 and 22 that can be used to sense cardiac activity and a defibrillation electrode 26 that may be use to stimulate (defibrillate). Intrathoracic electrodes on the transvenous catheter may be used for sensing and stimulation as well in a different configuration. Essentially all of the structure seen in applicant's specification with respect to figures 5-8 can be

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found in KenKnight's figures. To the extent applicant adequately shows how the first configuration accomplishes sensing and stimulation "capability" with a single subcutaneous lead and a single electrode as claimed in the absence of a transvenous electrode, KenKnight is capable of doing the same. The examiner considers the housing lead coupler 16 to be an interface. KenKnight teaches various electrode arrangements may be used and thus the controller and system is configurable thereto. Along with detecting tachycardiac and fibrillation and responding thereto KenKnight states that the therapy may be pacing as well. Since the can housing may be used in the treatments unipolar and bipolar electrode stimulation is envisioned. Pacing in general, which KenKnight can treat bradycardia and tachycardia. The various electrode arrangements provide for a multisite interface. The device includes a telemetry circuit for programming the device's operation and thus can be used to select configurations. The device may be configured to either treat with an atrial pulse or a ventricular pulse with different electrode configurations (column 3 lines 63-67) which constitute different functions. The electrodes are capable of sensing all of the intended use functions state in applicant's claim 33-40 sense sensing is the first step "associated" with detecting the intended uses. KenKnight teaches the transvenous lead may contain multiple electrodes, which possibly could be placed in a single chamber.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark W. Bockelman whose telephone number is (571) 272-4941. The examiner can normally be reached on Monday - Friday 10:00 to 6:30.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571) 272 -6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MWB

February 5, 2007

  
MARK BOCKELMAN  
PRIMARY EXAMINER